

Suggested Format for**Sub-Chronic and Chronic Toxicity Studies**

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

SUB-CHRONIC AND CHRONIC TOXICITY STUDIES	
Instructions to Create PDF	Document Format
Create Bookmarks for each item in the Document Format column.	<ul style="list-style-type: none">• Study Title Page,• Statement of Data Confidentiality <i>No confidentiality claims can be made for electronically submitted studies at this time,</i>• GLP Statement,• Flagging Statement if appropriate,• Table of Contents.
Create links in summary to related text and tables in body of study report or appendices. Create links to related text in results section and tables for each end point.	<ul style="list-style-type: none">• Executive Summary,<ul style="list-style-type: none">- Summary of Materials and Methods,- Summary of Results,- Maternal Toxicity (when applicable),- Offspring Toxicity (when applicable).• Materials and Methods,<ul style="list-style-type: none">- Materials- Procedure and Study Design,- Observations,- Data Analysis and Statistics.
Create links to related subject heading, text, tables, appendices, or supplemental files.	<ul style="list-style-type: none">• Results and Discussion,• Tables (see example list below),• Appendices,• Figures,• Supplemental Files.

Example Tables for Developmental Neurotoxicity Studies

Maternal Data Tables:

- Clinical Observations,
- Functional Observation Battery,
- Body Weights,
- Food Consumption,
- Litter data (size, mean weight, survival, etc.).

Offspring Data Tables:

- Clinical Observations
- Functional Observation Battery,
- Body Weight,
- Body Weight Gain,
- Developmental Landmarks,
- Auditory Startle Test,
- Motor Activity,
- Learning and Memory,
- Time and Cause of Death (if applicable).

Offspring Post Mortem Examination Tables:

- Gross Pathology,
- Brain Weights,
- Brain Dimensions,
- Microscopic Pathology,
- Morphometric Findings.